NOTICE

HSR Division | February 20, 2003 | Notice No. 0113

Required Human Subjects Research Education

Background

The Department of Energy (DOE/Office of Biological and Environmental Research (OBER)) has established a mandatory training program for all DOE contractors conducting research that involves human subjects. The purpose of this training, Collaborative IRB Training Initiative (CITI), is to ensure that all researchers and their responsible managers must understand and implement the rules, ethics, and practices required to conduct research with human subjects, their data, or biological specimens. This training currently includes 14 modules (see Table 1)— that must be completed. In addition, DOE requires the completion of additional modules as they are added to the training package. Researchers shall be notified as additional modules are added.

Researchers must be aware that this training does not replace NIH Human Subjects training or other required training.

This Notice is in effect until the publication of a LIR on Human Subjects Research. A Focus Team will be formed by June 1, 2003. If interested, contact Marilynn Thullen at mjthullen@lanl.gov or Laurie Wiggs at ldwiggs@lanl.gov.

Applicability

The requirements contained in this notice shall apply to all researchers (principal investigators (PIs), co-PIs, and key personnel), who are currently conducting or plan to conduct human subjects research. These requirements also shall apply to all members and staff of the Institutional Review Board (IRB)/HSR, the Associate Director for Operations (i.e., the Laboratory Institutional Official), and managers whose organizations conduct human subjects research.

Collaborators not affiliated with Los Alamos, must provide certification of required training from their institution. The IRB administrator reviews this certification and decides if additional training (selected modules) must be completed before initiation of the proposed research.

Requirements/ Instructions

All IRB/HSR members, IRB/HSR staff, and all researchers (PIs, Co-PIs, and key personnel) performing or intending to perform research with human subjects shall be required to complete the training according to the schedule in Table 2. In addition, Associate Director for Operations and the responsible managers in the organizations that conduct human subjects research must complete the training according to the required schedule in Table 2.

NOTE: Failure to complete training according to the schedule in Table 2, shall result in suspension or delay in approval of human studies research.

Table 1: List of Modules

The CITI Course in The Protection of Human Research Subjects contains modules addressing the following topical areas:	
Module 01:	History and Ethical Principles
Module 02:	Basic Institutional Review Board (IRB) Regulations and Review Process
Module 03:	Informed Consent
Module 04:	Social and Behavioral Research
Module 05:	Research Involving Records
Module 06:	Genetic Research in Human Populations
Module 07:	Research with Protected Populations – Vulnerable Subjects: A Definition
Module 08:	Research Involving Prisoners
Module 09:	Research Involving Children
Module 10:	Research Involving Pregnant Women and Fetuses in Utero
Module 11:	Population Risks, Group Harms, Community Consultation, and IRB Review – Research with American Indian, Alaska Native, and Other Socially Vulnerable Populations
Module 12:	FDA Regulated Research
Module 13:	Research Protections in the Department of Veterans Affairs
Module 14:	Hot Topics
Training can be found at the following website: www.miami.edu/citireg	

Table 2: Training Requirements

WHO	REQUIREMENT
IRB/HSR members and IRB/HSR Staff	Must complete training (modules 1-14) by June 1, 2003
Researchers conducting or commencing research prior March 1, 2003	Must complete training (modules 1-14) by December 31, 2003
Researchers commencing research during the period March 1, 2003 to December 31, 2003	Must complete training (modules 1-14) by December 31, 2003 or 3 months after research start date, whichever is later
Researchers commencing research after December 31, 2003	Must complete modules 1-7, prior to research start date and complete training, modules 8-14, within 6 months of research start date
Researchers joining in existing project	Must complete modules 1-14 within 3 months of appointment or December 31, 2003, whichever is later
Responsible managers of organizations currently conducting human subjects research and the Laboratory ADO	Must complete modules 1-3 by December 31, 2003
Responsible managers of organizations commencing human subjects research after March 1, 2003	Must complete modules 1-3 within 3 months of the research start date or December 31, 2003, whichever is later
New responsible managers or institutional officials	Must complete modules 1-3 within 3 months of appointment or December 31, 2003, whichever is later
Re-certification is required for all personnel covered by this policy within 2 years of completing the initial training.	

Current researchers, responsible managers, IRB members and staff must perform the following:

1. **Register for the CITI Course by March 1, 2003.**

   Guidance note: To register, participants should go to URL, www.miami.edu/citireg; select Los Alamos National Laboratory; complete the electronic registration form; and submit it for the CITI course. Within 24 hours, except on weekends and holidays, the new registrant will receive an e-mail notice containing a USERNAME, PASSWORD, and the URL for the course site. The notice will contain information about the CITI course including the learning objectives. There is no charge for the use of the program.

2. **Complete the training according to the schedule in Table 2.**

Researchers commencing work after March 1, 2003, new responsible managers, IRB members, and staff must perform the following:

1. **Register for the CITI Course.**

   Guidance note: To register for the course, participants should go to URL, www.miami.edu/citireg; select Los Alamos National Laboratory; complete the electronic registration form; and submit it for the CITI course. Within 24 hours, except on weekends and holidays, the new registrant will receive an e-mail notice containing a USERNAME, PASSWORD, and the URL for the course site. The notice will contain information about the CITI course including the learning objectives. There is no charge for the use of the program.

2. **Complete the training according to the schedule in Table 2.**

Questions?

Contact Marilynn Thullen, IRB/HSR Coordinator, Occupational Medicine, HSR-2, MS D421, 665-2658 (mjthullen@lanl.gov);

For NIH-related work, contact, Mary Ann D. Martinez in NIH Program Contact Office, B-DO, MS G758, 667-5324 (b_nih@lanl.gov).

References

- 45 CFR 46
- 10 CFR 745
- 21 CFR 50
- 21 CFR 56
- DOE Order 443.1, Protection of Human Subjects
- CITI Training website**, www.miami.edu/citireg**
- LPR 402-00-00.3 –Worker Health and Safety - Appendix 17, Occupational Medicine

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The OIC for this Notice is HSR-2, and the responsible division leader is the HSR-DL. This Notice shall remain in effect for 180 days or until the requirements have been incorporated into an LIR.